IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHEET METAL WORKERS NATIONAL HEALTH FUND, individually and on behalf of all others similarly situated, Plaintiff, v. AMGEN INC. and AMGEN USA INC., Defendants.	CASE NO. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff Sheet Metal Workers National Health Fund ("SMW Health Fund"), by its undersigned attorneys, hereby make the allegations in this Class Action Complaint against Defendants Amgen Inc. and Amgen USA Inc., (collectively, "Amgen" or "Defendants") concerning their acts and status upon actual knowledge, and concerning all other matters upon information, belief, and the investigation of their counsel:

I. SUMMARY OF CLAIMS

1. This antitrust action, brought under federal and state antitrust law, involves an anti-competitive tying arrangement and pricing scheme implemented by Amgen in the oncology clinic market. The scheme ties substantial purchases of Amgen's Red Blood Cell Growth Factor ("RBCGF") drug to its dominant White Blood Cell Growth Factor ("WBCGF") drugs. Both WBCGF and RBCGF drugs are needed by oncology clinics to treat cancer patients. The purpose of Amgen's scheme was and is to restrain competition and monopolize the market for sales of RBCGF drugs to oncology clinics. The result has been, and will continue to be, less price competition, less physician and patient choice and an increased expense to the public health system, including an increased price to Plaintiff and members of the Class who pay for or reimburse for treatment at oncology clinics.

2. Ortho sells Procrit. Amgen sells Aranesp. Both are RBCGF drugs that, prior to the implementation of Amgen's scheme, competed head-to-head in a two-player market. Annual combined sales to oncology clinics of these two products exceeded $2.8 billion in 2005.

3. Amgen also sells Neulasta and Neupogen, which are WBCGF drugs with a combined 98% market share of sales to oncology clinics. Amgen has a monopoly in the market for WBCGF drugs. Ortho does not sell a WBCGF drug.

4. Amgen's illegal pricing scheme penalizes oncology clinics on purchases of its monopoly WBCGF drug if the clinics do not purchase significant volumes of Amgen's Aranesp instead of Ortho's Procrit. From its inception in April 2004 through October 2005, Amgen's illegal pricing scheme caused Aranesp share to increase by 46%, to approximately 66% of the oncology clinic RBCGF drug market. Its market share has continued to increase.

5. On October 1, 2005, Amgen's pricing scheme became considerably more coercive and further restrained price competition in the RBCGF market. Amgen imposed, and continues to impose, even steeper pricing penalties on Amgen's monopoly WBCGF drugs when oncology clinics do not purchase 75% or more of their RBCGF drugs from Amgen. In fact, for a clinic to receive the same level of RBCGF and WBCGF drug rebates it received under the pre-October 1, 2005 contract, it had to increase its Aranesp share well above that amount.

6. Amgen's pricing scheme puts oncology clinics in a completely untenable position. A clinic will end up losing several hundred dollars per administration of Amgen's leading WBCGF drug because the cost of buying the drug (absent the contractual rebates) vastly exceeds the amount of government reimbursement. ***A clinic can only gain access to the rebates on Amgen's monopoly WBCGF drugs when it purchases virtually all of its RBCGF drug requirements from Amgen***.

7. Defendants' conduct constitutes a tying arrangement and/or restraint of trade in violation of federal and state antitrust law under either a *per se* or Rule of Reason analysis. As the result of Amgen's restraint of trade, Amgen's pricing scheme leaves oncology clinics with no economic alternative but to purchase virtually all RBCGF drugs from Amgen. The effect of this is to cause physicians to use Aranesp instead of the lower cost Procrit, which in turn raised the price to end payers – Plaintiff, other third-party payers and consumers.

8. Limiting payers' and clinics' access to Procrit is not in the public interest and has and will continue to harm payers and consumers. Physicians should not face economic coercion, and the healthcare system should not bear the increased costs of that coercion. Forcing oncologists to abandon the lower cost Procrit as the only economically viable way to gain access to another potentially life saving drug, is not, by any measure, in the public interest.

9. For these reasons, and to remedy the injuries that will be caused and have been caused by Amgen's anticompetitive conduct, Plaintiff seeks injunctive relief as well as treble damages.

II. JURISDICTION AND VENUE

10. This Court has personal jurisdiction over this lawsuit because Defendants have sufficient contacts with New Jersey to permit the exercise of jurisdiction in compliance with traditional notions of fair play and substantial justice. Defendants have offices in New Jersey, transact business in New Jersey, employ New Jersey residents, and hold memberships in New Jersey organizations and associations. Also, the acts complained of herein have substantial anticompetitive effects in this district.

11. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5,000,000 exclusive of interest and costs, and is a class action in which some members

of the Class are citizens of states different than Defendant. *See* 28 U.S.C. § 1332(d)(2)(A). Also, 28 U.S.C. §§ 1331, 1337, 2201 and 2002 give this Court subject-matter jurisdiction over Plaintiff's claims for violation of the Clayton Act, 15 U.S.C. § 26 and the Sherman Act, 15 U.S.C. §§ 1-2.

12. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)(2) and 15 U.S.C. §§ 15, 22 and 26, because Defendants have offices in New Jersey and transact business in New Jersey, and because acts or omissions giving rise to the claims set forth here occurred in and near this judicial district. Venue is also proper in this judicial district under L. Civ. R. 40.1(c), because this action is related to a case currently pending in this Court, *Ortho Biotech Products, L.P. v. Amgen, Inc. and Amgen USA, Inc.*, Civil Action No. 05-04850 (SRC-MF).

III. THE PARTIES

13. Plaintiff SMW Health Fund is a Taft-Hartley trust administered pursuant to the requirements of 29 U.S.C. § 186 by an equal number of trustees appointed by labor and union representatives. SMW Health Fund is a multiemployer welfare fund subject to ERISA. SMW Health Fund's office is located in Goodlettsville, Tennessee. At all relevant times, SMW Health Fund paid reimbursements for Aranesp administered in oncology clinics across the country.

14. Defendants Amgen Inc. and Amgen USA Inc. are corporations organized and existing under the laws of Delaware with their principal places of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen, among other things, manufactures and sells Aranesp as well as two WBCGF drugs, Neupogen and Neulasta.

IV. FACTUAL ALLEGATIONS

A. Ortho And Amgen Are The Only Competitors In The Sale Of RBCGF Drugs To Oncology Clinics Where Consumer Class Members Are Treated

1. Procrit

15. Severe anemia is most commonly seen in patients: (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy, or (3) undergoing zidovudine treatment for HIV disease. Anemia is caused by the depletion of the human hormone erythropoietin, which is produced primarily by the kidneys and stimulates red blood cell production and maturation in the bone marrow. Chemotherapy, for example, depresses erythropoietin production, often leading to anemia. Many patients suffering from anemia cannot lead normal, productive lives.

16. Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions.

17. Ortho sells Procrit, a branded version of epoetin alfa. By the Product License Agreement ("PLA") executed as of September 30, 1985, Amgen granted Ortho an exclusive license under Amgen's patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments except anemia in patients undergoing dialysis for end stage renal disease ("ESRD"). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field, which it does under the brand name Epogen.

18. Ortho secured FDA approvals, beginning in 1991, to market Procrit for the treatment of persons who develop anemia as a consequence of: (1) chemotherapy for cancer, (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases

in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.

19. Since Procrit was launched in 1991, it has been prescribed to millions who suffer from anemia included in the four indications listed above. As a result of Procrit's success, Ortho has paid Amgen over $1.5 billion in royalties on Procrit sales.

2. Aranesp

20. Amgen decided to circumvent the market exclusivity it had granted to Ortho to sell epoetin alfa for all purposes other than dialysis. The result was Amgen's introduction of Aranesp, a synthetic form of erythropoietin known as darbepoetin alfa. It was formulated by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia.

21. Ortho's work and investment in Procrit, which demonstrated the RBCGF drugs could be safely, effectively and widely used to combat chemo-induced anemia, helped Amgen to secure FDA approval of Aranesp and to sell Aranesp into markets in which physicians had been educated by Ortho about the benefits of RBCGF drugs.

22. Given the scope of Amgen's patents, Ortho and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Gross sales to oncology clinics for Procrit and Aranesp exceeded $2.8 billion in 2005.

B. Amgen Has A Monopoly On The Sale WBCGF Drugs

23. Many cancer patients undergoing chemotherapy may, for different reasons, also require a WBCGF drug to combat neutropenia, a white blood cell deficiency that is potentially life threatening. Neutropenia is a side effect of chemotherapy which potentially compromises a

patient's immune system. The disease occurs not only in many patients undergoing chemotherapy, but in individuals suffering from a number of other diseases.

24. Ortho does not sell a WBCGF drug, but Amgen does. Amgen sells two WBCGF drugs, Neupogen and Neulasta. The only other WBCGF drug sold is Leukine, which is distributed by Berlex Laboratories.

25. Neupogen was Amgen's initial WBCGF drug. In 2002, Amgen introduced Neulasta, a WBCGF product, which has been modified so that, according to Amgen, one injection of Neulasta is roughly equal to seven injections of Neupogen.

26. Amgen dominates the sales of WBCGF drugs which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product has been on the market for many years, it has only a *de minimus* share of WBCGF sales.

C. Amgen Has Monopolized The Sales Of RBCGF Drugs To Oncology Clinics By Leveraging Its WBCGF Drug Monopoly

1. Amgen begins bundled pricing on Aranesp and its WBCGF monopoly drugs

27. Virtually all oncology clinics administer both RBCGF and WBCGF drugs to patients. Given this fact and Amgen's monopoly on WBCGF drugs, these clinics must buy WBCGF drugs, particularly Neulasta, from Amgen.

28. This fact was not lost on Amgen as it developed a marketing plan for Aranesp. Amgen's strategy for selling Aranesp has been to penalize a clinic on the pricing of its dominant WBCGF drugs if the clinic did not purchase substantial amounts of Aranesp. The volume requirements in Amgen's pricing schemes for its RBCGF and WBCGF drugs are, in fact, disguised market share requirements designed to reduce Procrit's share of clinic sales by means other than competition on the price of RBCGF drugs or their relative merits.

2. The early 2004 Amgen contract

29. Amgen implemented the coercive pricing scheme at issue in the spring of 2004. At that time, Amgen began offering substantial "rebates" to oncology clinics on the condition that these facilities reach combined volume requirements for Amgen's RBCGF and WBCGF drugs. Amgen refers to these offerings on its RBCGF and WBCGF drugs as the Amgen Portfolio Contract ("APC").

30. Amgen's pricing to oncology clinics under its APC is broken into three groups – large, medium and small accounts – based on the amount of RBCGF and WBCGF drugs purchased. Each account is given dollar volume usage targets that, once reached, allow the clinic to earn a specified level of rebate. The dollar volume targets Amgen puts in each clinic's APC represent a specific percentage requirement of market share based on that clinic's historical usage. Rebates are earned when Amgen's share of the clinic's estimated total APC purchases reach those levels.

31. For example, under the APC in effect in the first half of 2004, a large account oncology clinic which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen received significantly greater rebates – a 25% rebate on its Aranesp purchases and a 25% rebate on Amgen's WBCGF drug purchases. An oncology clinic that did not meet its APC volume requirements would only receive a minimal rebate or discount.

3. The January 1, 2005 Amgen contract

32. Effective January 1, 2005, Amgen modified its APC. Amgen apparently recognized that simply providing an oncology clinic with a combined dollar volume target might

give the clinic the flexibility of loading up on Amgen's WBCGF drugs to meet its combined dollar volume target, rather than shifting its Procrit purchases to Aranesp. As a result, Amgen imposed restrictions on the amount of WBCGF drugs that could be considered for purposes of reaching the specified dollar volume targets or higher rebate levels. This forced oncology clinics to purchase more Aranesp, which was not subject to any incentive restrictions to reach higher rebate levels.

33. Amgen also required minimum dollar volume requirements for Aranesp. In addition, Amgen increased the rebates offered to oncology clinics, further penalizing those oncology clinics that failed to meet the dollar volume requirements set forth in each clinic's APC. With these changes to the APC, Amgen sought to more closely tie the rebates on its monopoly WBCGF drugs to the purchase of substantial amounts of Aranesp.

34. Under the revised APC, a large oncology clinic that purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive a 30% rebate on its Aranesp purchases and a 25% rebate on its WBCGF drug purchases.

35. All of these changes forced clinics to buy less Procrit and more Aranesp in order to get access to ***both*** the WBCGF and RBCGF rebates.

36. As a result of these pricing schemes, Ortho's share of sales to oncology clinics dropped precipitously. In the first quarter of 2004, Ortho had a 55% share of the oncology clinic market for RBCGF drugs and Amgen had a 45% share. By October 2005, Ortho's share had dropped to approximately 34%, with Aranesp having a 66% share.

37. This significant shift in relative market share was attributable to oncology clinics being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order for these customers to gain access to acceptable pricing on the WBCGF drugs they must buy from Amgen.

38. The effect of Amgen's coercive tying arrangements on sales of RBCGF drugs to oncology clinics is evidenced by comparing Procrit and Aranesp market shares to oncology clinics with their respective share of sales in another market – sales to retail drug stores – where Amgen has not introduced these tying arrangements. As a result, Procrit and Aranesp compete head to head without interference from Amgen's WBCGF monopoly drugs. Procrit's share of sales to retail drug stores was, and remains at, approximately 70%.

D. Amgen's New Pricing Scheme Is Designed To Eliminate Procrit From The Oncology Clinic Market

39. Having gained a 65% share of oncology clinic sales by tying access to WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen knew that it could further tighten its squeeze on this market. On October 1, 2005, Amgen's pricing scheme became significantly more coercive.

40. As with the previous pricing schemes, Amgen gave each clinic a series of dollar volume target levels for its total purchases of RBCGF and WBCGF drugs. As illustrated below for a typical large account, the more a clinic purchased, the greater rebate it received:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%
2	24.0%	19.0%	16.0%

1	23.5%	18.5%	15.0%
base level	23.0%	18.0%	14.0%

41. However, to gain access to even the lowest rebate level described above an oncology clinic was required to meet separate Aranesp and Neulasta dollar volume triggers. The threshold for Aranesp was set at dollar amounts equal to 65% of a clinic's prior RBCGF drug purchases (*i.e.*, 65% market share requirement), while the threshold for Neupogen and Neulasta was set at up to 100% of a clinic's prior purchases. Thus, to earn the minimum rebates required to avoid a loss on the administration of the WBCGF drugs to Medicare patients, a clinic has to buy Aranesp for at least 65% of its total RBCGF purchases.

42. A higher initial dollar volume threshold for Aranesp was only the start of the October 2005 pricing scheme. The scheme also was intended to coerce oncology clinics to purchase Aranesp for more than the minimum market share requirements. Under the modified APC, for an oncology clinic to receive the same aggregate value it had been receiving while performing under the pre-October 1, 2005 APC (described above), each clinic was required to purchase larger volumes of Aranesp in order to reach the higher levels of the rebate schedules. Moreover, the clinic's Aranesp purchases had to amount to at least 75% of its total RBCGF drug purchases to be eligible for the same level of rebates previously received. For example, for a large clinic, the top Aranesp rebate was 26%. This was 4% less than under the previous Amgen bundle, where a clinic could receive a 30% rebate. However, the clinic can earn back the additional 4% by taking its Aranesp share up to 75%. Thus, the 2005 pricing scheme was and is intended to raise the Aranesp levels well above the initial threshold number needed to qualify for any rebate.

43. This pricing scheme also reduced the highest Neulasta rebate from 25% to 21% for large clinics. As with the Aranesp rebates, an oncology clinic can earn back the 4% on Neulasta if 90% of its WBCGF drug purchases were of Amgen's Neulasta ***and*** the higher threshold for Amgen's Aranesp (up to 90%) was met.

44. The October 2005 pricing scheme continued to place limits on the amount of the WBCGF drugs that may be considered for purposes of determining rebate levels on gross purchases. Conversely, the APC did not place caps on Aranesp. This further drove oncology clinics to purchase all or substantially all of their RBCGF drugs from Amgen.

45. A clinic that did not meet its Aranesp volume requirement would only receive a 4% rebate on Neulasta. Previously, an oncology clinic that did not meet its Aranesp dollar volume target requirements in its APC nonetheless would receive a rebate of 7.1% to 9.5% on Neulasta. Thus, a non-conforming oncology clinic is being penalized an additional 3.1% to 5.5% on its Neulasta purchases under the October 2005 APC.

E. The Impact Of This Pricing Scheme On An Oncology Clinic's Medicare Business

46. Failing to meet the minimum Aranesp purchase requirements in the revised APC had severe economic consequences for oncology clinics. Because the use of WBCGF drugs had been established as the standard of care for treating neutropenia, oncology clinics had no choice but to carry Neulasta.

47. Medicare patients make up roughly 40% of the patient population treated in oncology clinics. As such, the economics of treating this patient group is a major consideration for any clinic. Without the Neulasta rebates (up to 25%), under the government's current reimbursement formula, an oncology clinic would have to pay Amgen hundreds of dollars more on treatment of Neulasta for a Medicare patient than the clinic will receive in reimbursement from the government and patients.

48. On January 1, 2005, the federal government changed the formula by which doctors and clinics are reimbursed for the drugs they purchase and administer in their offices. The formula is based on the drugs' average selling price ("ASP") plus 6%. Thus, if a clinic bought a drug that had an ASP of $1,000, the clinic would be reimbursed $1,060. This reimbursement amount is static regardless of what the particular clinic actually paid for the drug. The "plus 6%" is not intended to be profit to an oncology clinic. It is to provide the clinic with some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that require refrigeration, and bad debt from patients who do not make co-pays.

49. As the term suggests, the ASP of a drug is an average based on the prices paid – and discounts and rebates earned – by all purchasers of such drugs. Accordingly, a Medicare provider that does not, or cannot avail itself of all of the rebates offered by a manufacturer can end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider will be reimbursed by the government (ASP + 6%). Where the price paid exceeds the reimbursement amount, the provider actually realizes a loss on the acquisition of a particular drug.

50. Unless an oncology clinic qualifies for Amgen's rebates, this is precisely the situation the clinic will face when it administers Neulasta, Amgen's dominant WBCGF product, as the following example illustrates: Neulasta's list price is $2,603.00. The Medicare reimbursement (*i.e.*, ASP + 6%) per unit of Neulasta was $2,078.066 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount is 20.17% or $524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis, the clinic had to receive rebates and

discounts equal to 20.17% below Amgen's list price. Amgen currently provides oncology clinics with just a 5% discount off list price and a 4% rebate if the clinics fail to buy the requisite levels of Aranesp specified in their modified APC. In other words, unless the clinics meet the Aranesp volume requirements, the clinic will pay Amgen $295.87 more ***per administration*** of Neulasta than the clinic is being reimbursed by the government.

51. The foregoing example is based on Neulasta's list price as of October 2005. Amgen has since increased the list price of Neulasta, which would result in oncology clinics losing even more money if they fail to meet Amgen's purchase requirements.

52. Amgen's latest pricing scheme has forced and will force oncology clinics to attempt to meet Amgen's enhanced dollar volume requirements for Aranesp, which translate into substantial market share requirements. This creates a strong incentive on the part of the oncology clinic to stock only Aranesp, or to reduce dramatically the level of Procrit stocked, and ultimately to harm competition and raise prices paid by end payers. Few oncology clinics are able to bear the cost and financial risk of also stocking Procrit given the level of Amgen's dollar volume requirements for Aranesp. An oncology clinic that wanted to use even a small amount of Procrit would need to stock both Procrit and Aranesp but would have to carefully manage and monitor relative usage of Aranesp and Procrit, with severe financial consequences should it err in this process. Most oncology clinics are in no position to take such risks.

53. Amgen's current efforts to leverage its monopoly in the WBCGF drug market by penalizing oncology clinics that do not buy substantial amounts of Aranesp, coupled with the Medicare reimbursement regime, preclude Ortho from competing over the long-term in the RBCGF oncology clinic market. One Amgen official already has boasted to a Procrit customer that they expect 75% of existing Procrit customers will agree to Amgen's latest pricing scheme.

Amgen had secured nearly 65% of RBCGF drug sales in the oncology clinic market before implementing its latest version of the APC. Amgen's coercive revisions have enabled it to increase and maintain its monopoly share in the RBCGF drug oncology clinic market.

F. Ortho's Ability To Respond Competitively Is Constrained By Amgen's Tying Arrangement

54. Ortho is an equally efficient competitor. But given the way in which government reimbursement works for a large percentage of a clinic's patients, Amgen's scheme of tying rebates on its monopoly drug to purchases of its RBCGF drug effectively precludes Ortho from responding with commensurate price cuts, causing Plaintiff to pay higher prices for RBCGF drugs.

55. As alleged above, the government's reimbursement formula for Medicare patients for Procrit and Aranesp is based on each product's ASP plus 6%. Absent Amgen's tying arrangements in which WBCGF rebates are tied to Aranesp purchases, price competition between Aranesp and Procrit (in the form of discounts or rebates) would have resulted in Aranesp and Procrit each having a lower ASP as calculated by the government. Here, the rebates provided on Neulasta, while tied by Amgen to an oncology clinic buying a certain volume of Aranesp, have not been, and will not be, considered as the Aranesp ASP is calculated by the government. As a result, offering Neulasta rebates tied to Aranesp purchases allows Amgen to make it financially attractive to buy Aranesp, but in a way which avoids the corresponding effect of a lower Aranesp ASP (which, in turn, provides an oncology clinic with a smaller cushion, in dollar terms, on reimbursement for Aranesp, *i.e.*, 6% of a lower ASP).

56. Put simply, by tying together rebates on WBCGF drugs with purchases of Aranesp, Amgen forces Ortho to absorb on its one product the discounts Amgen has spread over two products. The result of Ortho having to absorb discounts on its one product, Procrit, is that it

will drive Procrit ASP down and, correspondingly, the level of government reimbursement on Procrit. Because, however, the WBCGF rebates are a disguised way of discounting Aranesp, the Aranesp ASP will not go down correspondingly.

57. The lack of parity in the lowering of the ASPs of Procrit and Aranesp – because of the Amgen tie – effectively precludes price competition. If Ortho were to offer a discount on Procrit commensurate with discounts offered by Amgen on its WBCGF and RBCGF drugs, a lower ASP for Procrit would be recalculated by the government at subsequent reporting intervals. (ASPs are recalculated each quarter based on pricing data from two quarters earlier.) Procrit would then have to offer an additional discount on the lower ASP because an ASP plus 6% reimbursement on a lower ASP provides the clinic with less money to cover its costs (*i.e.*, 6% of a lower ASP). While Ortho would be required to make up the difference in dollars to oncology clinics under a lower Procrit ASP, Amgen would not on Aranesp. Amgen's rebates are tied to its WBCGF drugs and, therefore, Amgen could match any incremental margin created by Procrit discounting with incremental incentives on its WBCGF drugs. Consequently, the Aranesp ASP would not drop to the same extent as Procrit's. The result of Procrit having a lower ASP than Aranesp is that Ortho would be forced to continue to chase Procrit's ASP down – each drop in the Procrit ASP will require an additional discount on the lower ASP to make up the dollar discount to oncology clinics to cover their costs. Meanwhile, the Aranesp ASP has remained and would remain stable because Amgen's WBCGF rebates do not affect the Aranesp ASP, although they are tied to and driving Aranesp sales. The Procrit price spiral would result in Ortho pricing Procrit below cost in order to match Amgen's rebates on its WBCGF and RBCGF drugs.

58. On January 1, 2006, the government moved hospital reimbursement for Medicare outpatients to an ASP reimbursement system. Hospitals reportedly will be reimbursed at ASP plus 6%. The adoption of an ASP reimbursement system in hospitals allows Amgen to introduce into hospitals the same pricing scheme it is now using to foreclose price competition in the sale of RBCGF drugs to oncology clinics. Amgen may, again, simply leverage its monopoly in WBCGF drugs to provide, in effect, rebates on Aranesp without impacting the Aranesp ASP.

G. Procrit Is A Highly Effective Drug

59. Extensive clinical trials have repeatedly demonstrated Procrit's effectiveness in the treatment of anemia, and millions of Americans have been administered Procrit over the past 14 years. Recent studies and reports continue to underscore Procrit's efficacy.

60. In May 2005, the results of a comparative clinical trial involving Aranesp and Procrit designed specifically to measure the rate of hemoglobin improvement were presented at the annual meeting of the American Society of Clinical Oncology ("ASCO"). The study authors, led by Dr. Roger Waltzman of Saint Vincent's Comprehensive Cancer Center, concluded: (1) a trend toward a lower rate of transfusion in Procrit-treated patients when compared to Aranesp-treated patients, and (2) a significant difference between treatments in the total number of red blood cell units transfixed, with Procrit-treated patients requiring far fewer units per patient transfused than Aranesp-treated patients.

61. Aside from the expense, time and invasive nature of the procedure, transfusions present numerous medical risks. Chemotherapy patients are significantly benefited by a reduction in the number of transfusions and the amount of blood transfused, as is the health care system as a whole since the available blood supply for emergency use in other patients is not otherwise depleted.

62. At the May 2005 ASCO meeting, there was a presentation on a comparative study of Procrit and Aranesp sponsored by Amgen and led by Dr. John Glaspy of the University of California at Los Angeles. The study was designed to find "non-inferiority" of either product if the level of transfusions fell within a broad range. Having defined equivalence in these broad terms, the study concluded that Procrit and Aranesp were not inferior to one another.

63. At the May 2005 ASCO meeting, there was another presentation based on an independent, retrospective chart review conducted by Dr. A.S. Case with the University of Alabama at Birmingham. The review was directed at determining the transfusion rates after treatment with Procrit and Aranesp. Based on this observational data, the authors found that a significantly lower proportion of patients required transfusions, and fewer total units were transfused, when treated with Procrit rather than Aranesp.

H. Amgen's Pricing Schemes Have Injured Plaintiff And Competition As A Whole

64. Amgen's pricing schemes have caused and will continue to cause anti-competitive effects in the relevant product markets. Amgen economically coerces oncology clinics to purchase its RBCGF product, Aranesp, as a condition for receiving substantial price rebates and products that they must purchase from Amgen – WBCGF drugs. Unless they purchase significant amounts of their RBCGF drugs from Amgen, oncology clinics will not qualify for the massive rebates provided on Amgen's dominant WBCGF drugs. Moreover, if they agree to buy virtually all of their RBCGF and WBCGF drugs from Amgen, oncology clinics are given even higher rebates. The only economically viable option for these oncology clinics is to purchase all or nearly all of their RBCGF drugs from Amgen, even though many physicians would prefer Procrit if Aranesp competed head-to-head with Procrit.

65. Amgen's coercive bundling programs have caused public and private health care insurers, including third-party payer members of the Class, to reimburse clinics for their Aranesp purchases at rates that are higher than would have prevailed in "head-to-head" competition.

66. Moreover, Amgen's actions substantially foreclose Ortho from selling Procrit to oncology clinics. This foreclosure is demonstrated by the significant market share shift that has occurred and will continue to occur as a result of Amgen's latest pricing scheme.

67. Amgen's tying arrangement and restraint of trade would also require potential RBCGF drug competitors to price their product below any true measure of cost in the pharmaceutical industry, even if these potential competitors were as efficient as Amgen. In this manner, Amgen's tying arrangement has caused and will continue to cause anticompetitive effects by increasing the barriers to entry into RBCGF drug markets.

I. There Is No Legitimate Business Justification For Amgen's Tying Arrangement Or Its Pricing Scheme

68. There is no legitimate business purpose or efficiency justification for Amgen's pricing schemes. Amgen has employed these schemes for the sole purpose of eliminating Ortho and potential entrants as competitors in the sale of RBCGF drugs to oncology clinics.

J. Sales Of RBCGF Drugs To Oncology Clinics Constitute A Relevant Product Market

69. RBCGF drugs are sold through various channels. The roughly 2,300 oncology clinics in the United States represent the largest market for Procrit and Aranesp, with over $3.8 Billion in gross sales projected in 2005. "Oncology clinics" include the small number of "mixed use" clinics that provide oncology as well as other clinic services.

70. To be successful, a seller of RBCGF drugs must have a strong presence in oncology clinics. These clinics, which are often owned and operated by oncologists in private practice, are the preferred venue for patients to receive outpatient administration of RBCGF

drugs as well as WBCGF drugs. At present, the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics.

71. Both Amgen and Ortho have historically treated oncology clinics as a distinct market. Amgen and Ortho participate in audits of epoetin alfa sales designed to align dialysis (Epogen) and non-dialysis Procrit sales in accordance with the license. The audit methodology was formulated by Amgen. It treats oncology clinics as a distinct market segment because oncology clinics use RBCGF drugs exclusively to treat anemia associated with non-dialysis indications. Because the non-dialysis indications belong to Ortho under the PLA, the audit treats all sales to oncology clinics of both parties' brands of epoetin alfa (Epogen or Procrit) as belonging to Ortho.

72. Amgen and Ortho have also recognized oncology clinics as a distinct market in their pricing. The pricing scheme that is the subject of this Complaint is being offered only to oncology clinics, and Amgen has used this distinction in other pricing programs. For instance, in the past, Amgen offered hospitals 30% "off invoice" discounts for the purchase of Aranesp, but did not offer oncology clinics this favored "off invoice" pricing.

73. An analysis of prices for Procrit shows that oncology clinics on average pay roughly 5% more for the drug than hospitals do.

74. Hospitals cannot buy more RBCGF drugs than they need and "arbitrage" a portion of their purchases by reselling to oncology clinics. It has been a longstanding practice in the pharmaceutical business to have "own use" clauses in sales contracts precluding resale for profit.

75. Government health care programs, such as Medicare, also treat oncology clinics differently than other purchasers. The amount of reimbursement and the formula utilized by the

government for oncology clinics are different than that which are used for other industry participants, such as hospitals.

76. Most oncology clinics purchase drugs through entities called "specialty distributors." Specialty distributors deliver oncology drugs, which often require careful handling (*e.g.*, refrigeration), to thousands of oncology clinics. These specialty distributors are licensed to distribute to oncology clinics.

77. Oncology clinics have formed their own Group Purchasing Organizations ("GPO") to negotiate with drug manufacturers. Historically, certain purchasers of pharmaceuticals have benefited from collectively bargaining with drug manufacturers through GPOs. Hospitals, for instance, belong to GPOs. These hospital GPOs generally do not permit oncology clinics to participate. In recent years, oncology clinics began to form specialized GPOs in an effort to achieve lower prices.

78. The sale of RBCGF drugs to oncology clinics is a market recognized by industry and government.

79. There are high barriers to entry in the sale of RBCGF drugs. Foremost are Amgen's exclusive patent rights over epoetin alfa. A market entrant would have to commit massive resources to fund clinical research to: (1) demonstrate the safety and effectiveness of a new drug, (2) secure regulatory approval for its distribution in the United States, (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

K. Sales Of WBCGF Drugs To Oncology Clinics Constitute A Distinct And Separate Product Market

80. The sale of WBCGF drugs in the United States is a relevant product market separate and distinct from the sale of RBCGF drugs.

81. WBCGF drugs are unique products, as they are the only products that alleviate the symptoms associated with treatment-induced neutropenia.

82. The sale of WBCGF drugs to oncology clinics is a market recognized by industry and government.

83. There are high barriers to entry in the sale of WBCGF drugs. There are no potential entrants on the horizon. Any potential competitor to Amgen's WBCGF drug monopoly would face what Amgen claims is a broad patent portfolio. Therefore, to enter these markets, an entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) and secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

L. Amgen Achieved A Monopoly In The Sale Of RBCGF Drugs To Oncology Clinics And Currently Maintains This Monopoly

84. Amgen achieved a monopoly in the sales of RBCGF drugs to oncology clinics through the unlawful and economically coercive conduct of conditioning the receipt of substantial price rebates on the WBCGF drugs that clinics must purchase from Amgen on the purchase of Amgen's RBCGF drug Aranesp. In October 2005, Amgen's market share of sales of RBCGF drugs to oncology clinics was 66% of the market share. Amgen has since increased and maintained its monopoly share in the RBCGF drug market.

V. CLASS ACTION ALLEGATIONS

85. Plaintiff brings this action on behalf of themselves and, pursuant to Rule 23 of the Federal Rules of Civil Procedure, as representatives of a class (the "Class" or "Plaintiff Class") defined as:

> All persons and entities in the United States and its territories who paid all or a portion of the cost for Aranesp administered in an oncology clinic during the period April 2004 to the present.
>
> Excluded from the Class are those who make flat co-pays and those whose co-pay was fully reimbursed by an insurer or other third party.

86. The Class is so numerous that joinder of each of the members of the Class would be impracticable. There are thousands of third-party payers who made payments for Aranesp and tens of thousands of consumers who did so as well.

87. There are questions of law and fact which are common to the claims of Plaintiff and the Class, which predominate over questions affecting only individual Class members. These common questions include, but are not limited to:

a. Whether Defendants' conduct violated federal and state antitrust laws;

b. Whether, and to what extent, the conduct of Defendants caused injury to Plaintiff and members of the Class, and, if so, the appropriate measure of damages; and

c. Whether Plaintiff and members of the Class are entitled to injunctive relief.

88. Plaintiff's claims are typical of the claims of the members of the Class, in that Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

89. Plaintiff will fairly and adequately assert and protect the interests of the Class. Plaintiff's interests coincide with, and are not antagonistic to, the interests of the other members of the Class.

90. Plaintiff's counsel are experienced and competent in the prosecution of complex class action litigation.

91. The questions of law and fact which are common to the claims of Plaintiff and the Class predominate over questions, if any, that may affect only individual members of the Class because, among other reasons, Defendants have acted on grounds generally applicable to the entire Class.

92. This class action would preclude the potential for inconsistent or contradictory individual judgments that would dispose of or impair the interests of other prospective Class members not parties to individual litigation. This class action would establish compatible and consistent standards of conduct for Defendants.

93. Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making final injunctive relief or corresponding declaratory relief appropriate with respect to the Class as a whole.

94. Class action treatment is the superior (if not the only) method for the fair and efficient adjudication of this controversy because, among other reasons, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding by means of class action, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh the difficulties, if any, which may arise in the management of this case as a class action.

VI. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF
(Declaratory And Injunctive Relief Under § 16 Of The Clayton Act)

95. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

96. Defendants' conduct, as detailed herein, constitute violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1.

97. Defendants and their co-conspirators agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and non-competitive levels, the price of Aranesp and lessened competition in the relevant market.

98. The acts committed by Defendants and their co-conspirators as alleged herein unlawfully restrained interstate and foreign commerce and are against public policy.

99. Plaintiff and the members of the Class were injured by reason of unlawful acts of Defendants and their co-conspirators as alleged herein.

100. Plaintiff and the members of the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Section 2 of the Sherman Act.

101. Plaintiff and the members of the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

SECOND CLAIM FOR RELIEF
(*Per Se* And Rule Of Reason Unlawful Tying In Violation Of California § 16700 Or, Alternatively, State Antitrust Laws)

102. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

103. Amgen is a Delaware corporation with its principal place of business in the State of California and is subject to the laws of the State of California.

104. As corporations that maintain their principal place of business in the State of California, Defendants have a reasonable likelihood of being sued with the State of California for the wrongful conduct in which they have engaged.

105. The Cartwright Act, § 16755, provides as follows: "Any violation of this chapter is a conspiracy against trade . . ." Plaintiff is empowered by the Cartwright Act § 16750 to commence a private action for up to three times their damages due to the injuries they have suffered and continue to suffer as a result of Defendants' violations of the Cartwright Act. The Cartwright Act further states:

> Any person who is injured in his or her business or property by reason of anything forbidden or declared unlawful by this chapter, may sue therefore . . . and [is entitled] to recover three times the damages sustained by him or her, [including] interest[.]

Cal. Bus. & Prof. Code § 16750(a).

106. Plaintiff is a "person" within the meaning of the Cartwright Act as defined in § 16702.

107. Defendants acted with specific intent to obtain monopoly power in the relevant market. In addition, Defendants have profited significantly from the aforesaid monopolization and attempted monopolization. Defendants' monopolistic profits come at the expense and detriment of the Plaintiff and members of the Class.

108. Amgen has engaged in an unlawful contract, combination, conspiracy and agreement in unreasonable restraint of trade and commerce, in violation of California Bus. & Prof. Code § 16700, *et seq.* This includes agreements with oncology clinics that force them to purchase all or nearly all of their demand for RBCGF drugs from Amgen.

109. The product characteristics, uses and character of demand for RBCGF drugs (which are used to treat chemotherapy-induced anemia but not neutropenia) are different from

the product characteristics, uses and the character of demand for WBCGF drugs (products that treat neutropenia, but not anemia). RBCGF and WBCGF drugs are distinct products: they are used to treat different conditions and are not functionally interchangeable.

110. At all times relevant to this action, Amgen has had market power in the sale of WBCGF drugs sufficient to force oncology clinics that purchase WBCGF drugs to also purchase Aranesp regardless of whether these purchasers actually preferred Procrit.

111. A substantial amount of interstate commerce has been and is being affected by Amgen's tying arrangement. The total purchases of RBCGF drugs by oncology clinics was projected to exceed $2.8 Billion in 2005.

112. Amgen's tying arrangement forces oncology clinics to purchase all or nearly all of their demand for RBCGF drugs from Amgen in a tied package with Amgen's WBCGF drugs. Pursuant to Amgen's pricing schemes, which offer significant rebates for the purchase of Amgen's dominant WBCGF drugs if they are purchased in a package with large quantities of Aranesp, the only economically viable option for oncology clinics that need WBCGF drugs increasingly is for them to purchase all or nearly all of their RBCGF drugs from Amgen.

113. Amgen's tying arrangement has substantially foreclosed and will continue to substantially foreclose Ortho from competing with Amgen for the sale of RBCGF drugs to oncology clinics based on the efficacy of its product and the price of its product on a stand-alone basis.

114. Amgen's tying arrangement has no legitimate business purpose. It achieves no legitimate efficiency benefits and has the anticompetitive effect of foreclosing competition on the merits for the sale of RBCGF drugs to oncology clinics.

115. Amgen's tying arrangement has adversely affected competition in the sale of RBCGF drugs to oncology clinics and has increased the cost to consumers in this market and will continue to do so unless enjoined.

116. Amgen's restraint of trade has been effectuated by a variety of unlawful conduct undertaken with the purpose and effect of eliminating competition in the sale of RBCGF drugs, including but not limited to:

- Conditioning the sale of RBCGF drugs on the purchase of WBCGF drugs;
- Granting rebates on the sale of WBCGF drugs conditioned upon the purchase of RBCGF drugs from Amgen;
- Granting multi-product rebates conditioned upon meeting disguised market share requirements for RBCGF and WBCGF drugs; and
- Entering into agreements that have the purpose and effect of requiring customers to purchase all or almost all of their requirements for RBCGF drugs from Defendants.

117. Amgen's exclusionary practices have caused and will continue to cause substantial anticompetitive effects on the sale of RBCGF drugs to Plaintiff. Amgen's conduct has substantially foreclosed and will continue to substantially foreclose competition from Ortho in the sale of RBCGF drugs to Plaintiff. Amgen's conduct has raised and will continue to raise barriers to entry for potential competitors for the sale of RBCGF and WBCGF drugs.

118. Amgen's practices have no legitimate business justification and pose no pro-competitive benefit, and Plaintiff paid higher prices for RBCGF drugs as a result.

THIRD CLAIM FOR RELIEF
(Violation Of California's Unfair Competition Law,
Business And Professional Code § 17200, *Et Seq*.)

119. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

120. Defendants' actions constitute unfair and deceptive unlawful practices committed in violation of the Unfair Competition Law, Bus. & Prof. Code §§ 17200, *et seq*.

121. Defendants violated the "fraudulent," "unfair" and "unlawful" prongs of § 17200 by engaging in the conduct described above that is subject to revision upon the completion of discovery.

122. Defendants are licensed to do business in the State of California and California is Defendants' principal place of business. As such, Defendants maintain a reasonable expectation of being sued in California under California's laws for their illegal conduct.

123. As a direct and proximate result of Defendants' conduct, Plaintiff and the Class members have been injured in an amount to be proven at trial.

FOURTH CLAIM FOR RELIEF
(Violation Of State Antitrust Laws)

124. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

125. To the extent the Court rules that California's antitrust law does not apply nationwide, Plaintiff alleges that:

a. Defendants' aforementioned practices violated Alabama Code § 6-5-60, *et seq*.;

b. Defendants' aforementioned practices violated Alaska Stat. 45.50.580(a) & (b);

c. Defendants aforementioned practices violated Arizona Revised Stat. Code §§ 44-1401 *et seq.*

d. Defendants aforementioned practices violated District of Columbia Code Ann. §§ 28-4503 *et seq.*

e. Defendants' aforementioned practices violated the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*;

f. In this complaint, Plaintiff does not allege a violation of Hawaii Rev. Stat. 480-1 *et seq.*, but seeks to comply with the procedural prerequisites in Haw. Rev. Stat. 480-13.3, to file and maintain a private indirect-purchaser class action.

g. Defendants' aforementioned practices violated Iowa Code §§ 553.1 *et seq.*

h. Defendants' aforementioned practices violated Kansas Stat. Ann. §§ 50-101 *et seq.*

i. Defendants' aforementioned practices violated the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*;

j. Defendants' aforementioned practices violated the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51-121, *et seq.*;

k. Defendants' aforementioned practices violated 10 Maine Rev. Stat. §§ 1101 *et seq.*

l. Defendants' aforementioned practices violated the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93;

m. Defendants' aforementioned practices violated Michigan Comp. Laws. Ann. §§ 445.773 *et seq.*

n. Defendants' aforementioned practices violated Minnesota Stat. §§ 325D.52 *et seq.*

o. Defendants' aforementioned practices violated Mississippi Code Ann. § 75-21-1 *et seq.*

p. Defendants' aforementioned practices violated Nebraska Rev. Stat. §§ 59-801 *et seq.*

q. Defendants' aforementioned practices violated Nevada Rev. Stat. Ann. §§ 598A *et seq.*

r. Defendants' aforementioned practices violated the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-1, *et seq.*;

s. Defendants aforementioned practices violated New Mexico Stat. Ann. §§ 57-1-1 *et seq.*

t. Defendants' aforementioned practices violated New York Gen. Bus. Law § 340 *et seq.*

u. Defendants' aforementioned practices violated North Carolina Gen. Stat. §§ 75-1 *et seq.*

v. Defendants' aforementioned practices violated North Dakota Cent. Code §§ 51-08.1-01 *et seq.*

w. Defendants' aforementioned practices violated South Dakota Codified Laws Ann. §§ 37-1 *et seq.*

x. Defendants' aforementioned practices violated Tennessee Code Ann. §§ 47-25-101 *et seq.*

y. Defendants' aforementioned practices violated Vermont Stat. Ann. 9 §§ 2453 *et seq.*

z. Defendants' aforementioned practices violated West Virginia Code §§ 47-18-1 *et seq.*

aa. Defendants' aforementioned practices violated Wisconsin Stat. §§ 133.01 *et seq.*

126. As a direct and proximate result of Defendants' unlawful conduct, Class members in each of these States have been injured in their businesses and property in that they paid more for the drugs at issue than they would have paid absent Defendants' unlawful conduct.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. That the Court declare, adjudge and decree that Amgen has committed the violations of law alleged herein;

B. That the Court award to Plaintiff the damages sustained as a result of the illegal conduct of Amgen, in an amount to be proved at trial, to be trebled according to law, plus interest (including prejudgment interest), attorneys' fees and costs of suit, and such other and further relief as this Court may deem just and proper.

DATED: November 2, 2007

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

DATED: November 2, 2007

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